IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

STATE OF Illinois)
) SS. **AFFIDAVIT OF LIANA RADTKE**
COUNTY OF _Winnebago)

LIANA RADTKE, being first duly sworn, according to law, and having personal knowledge of the matters contained herein, deposes and states as follows:

1. I am currently the Senior Regulatory and Compliance Director for UDL Laboratories, Inc. ("UDL").

2. UDL is an Illinois corporation with its principal place of business in Illinois.

3. On April 24, 2008, UDL was informed of a voluntary Class I recall of all marketed lots of Digitek® tablets within expiry by the manufacturer, Actavis Totowa LLC. UDL distributed Digitek® for Actavis under the UDL label.

4. As the Senior Regulatory and Compliance Director, I was UDL's primary contact with the FDA regarding the Digitek® recall.

5. On or about April 24, 2008, UDL retained the services of Stericycle, Inc. for distribution of the Digitek® recall notification packet and consumer product return kit and tracking of the recalled product.

6. The recall notification packet was initially sent out to over 42,000 wholesalers, pharmacies, hospitals, clinics, and long-term care facilities, as well as to approximately 106 UDL direct accounts.

7. The recall notification packet identified the product, the reason for the recall, and action items. Recipients of the recall notification packet were instructed to "identify your retail-level customers and notify them at once of this product recall"; and retail-level customers who had further distributed the recalled product were to "instruct the consumer to contact Stericycle at 1-888-473-8015 for the return of the product." *See* Exh. A, recall notification packet. Further instructions included carrying out a physical count of recalled product, recording the data on a business reply card, and returning recalled product to Stericycle facilities in Indiana. *Id.*

8. In conjunction with the mailing of the recall notification packets, the Food & Drug Administration requested that UDL perform a Level A (100%) effectiveness check on wholesalers, pharmacies, hospitals, clinics, and its direct accounts. For the effectiveness checks, outbound calls were placed to 32,912 non-responders to see if they received the recall notification packet, had any affected product (if so, a return kit is sent), or if the non-responders had any other questions or comments.

9. UDL submitted recall status report updates to the FDA approximately every six weeks, and began the Level A effectiveness check in mid-July 2008.

10. In or about November 2008, Stericycle completed the effectiveness check, which resulted in 25,670 customers responding to the questionnaire. From the effectiveness check Stericycle learned that 322 facilities had closed; 1294 customers could not be contacted; and 5,626 customers were uncooperative.

11. As of February 10, 2010, Stericycle has received 10,374 business reply card responses and/or product returns from pharmacies, hospitals, clinics, and UDL direct accounts, which included of 2,581,793 units/tablets.

12. Stericyle received 13,253 inquiries from consumers. Only 5,936 consumers requested a consumer product return kit.

13. Upon request, consumers received a "Digitek® Consumer Return Kit" outlining the requisite steps to receive a refund on recalled product. *See* Exh. B, Consumer Return Kit. Consumers returning unused Digitek®, together with a valid pharmacy receipt received a refund for the last prescription filled; consumers who provided a valid pharmacy receipt, but destroyed or disposed of remaining Digitek®, also received a refund. Consumers without a valid pharmacy receipt could also receive a refund on a per-tablet basis.

14. Although the Consumer Return Kit indicates that the required documents (consumer authorization form and receipt) and return of product must be completed and postmarked no later than October 31, 2008 to be eligible for a refund, Stericycle has continued to process and reimburse returns to date.

15. As of February 10, 2010, Stericycle had received 8,905 responses by product returns from consumers, which included 457,632 units/tablets.

FURTHER AFFIANT SAITH NAUGHT.

Liana Radtke
LIANA RADTKE

SWORN TO AND SUBSCRIBED IN MY PRESENCE this 17th day of February, 2010.

NOTARY PUBLIC

073021.000031.1114018.1

OFFICIAL SEAL
TIMOTHY G WAIT
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:05/10/11

Any Business Name
Any Street
Any City, XX 12345

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO 2702 INDIANAPOLIS IN

POSTAGE WILL BE PAID BY ADDRESSEE

STERICYCLE INC
6026 LAKESIDE BLVD
INDIANAPOLIS IN 46209-7912

STERICYCLE
(800) 668-4391
2670 EXECUTIVE DR SUITE A
INDIANAPOLIS IN 46241

LTR 1 OF 1

ATTN: PHARMACY MGR / RECALL COORD

SHIP TO: N/A
ANY BUSINESS NAME
ANY STREET

ANY CITY XX 12345

NY 122 9-02

UPS NEXT DAY AIR SAVER

TRACKING: 1Z E38 095 13 2533 7828

1P

BILLING: P/P

N22960018D1864-2

URC75.5A 02/2008

EXHIBIT A

Digitek® (digoxin tablets, USP)

NDC # / BOX	NDC# / CARD / BLISTER	STRENGTH	SIZE	WHOLE CARDS OR PACKS ON HAND	PARTIAL CARDS OR PACKS ON HAND	TABLET COUNT PER PARTIAL CARDS OR PACKS ON HAND
51079-945-20	51079-945-01	125 mcg (0.125 mg)	UD100			
51079-945-57	51079-945-30	125 mcg (0.125 mg)	UD300			
51079-945-56	51079-945-30	125 mcg (0.125 mg)	PC300			
51079-945-66	51079-945-63	125 mcg (0.125 mg)	CP180			
51079-946-20	51079-946-01	250 mcg (0.25 mg)	UD100			
51079-946-66	51079-946-63	250 mcg (0.25 mg)	CP180			

BUSINESS REPLY CARD

UDL LABORATORIES INC.

April 28, 2008

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, even if you do not have the recalled product. Thank you.

Signature _____ Title _____

Name _____ Phone _____

Event 1864
ID 22960018
Any Business Name

Digitek® (digoxin tablets, USP)

NDC # / BOX	NDC# / CARD / BLISTER	STRENGTH	SIZE	WHOLE CARDS OR PACKS ENCLOSED	PARTIAL CARDS OR PACKS ENCLOSED	TABLET COUNT PER PARTIAL CARDS OR PACKS ENCLOSED
51079-945-20	51079-945-01	125 mcg (0.125 mg)	UD100			
51079-945-57	51079-945-30	125 mcg (0.125 mg)	UD300			
51079-945-56	51079-945-30	125 mcg (0.125 mg)	PC300			
51079-945-66	51079-945-63	125 mcg (0.125 mg)	CP180			
51079-946-20	51079-946-01	250 mcg (0.25 mg)	UD100			
51079-946-66	51079-946-63	250 mcg (0.25 mg)	CP180			

PACKING SLIP

UDL LABORATORIES, INC.

April 28, 2008

The following information is required to assure proper crediting:

Wholesaler Debit Memo: _____

Event 1864
ID 22960018
Any Business Name

Ship To: STERICYCLE RECALL COORDINATOR
2670 EXECUTIVE DRIVE SUITE A
INDIANAPOLIS IN 46241

RS
22960018
1864

IN 462 9-01

UPS GROUND
TRACKING: 1Z E38 010 06 9193 2545

023 (10/06)

PACKING INSTRUCTIONS:

1. Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.

2. Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)

3. Keep this for your records. All followup will be based on this shipping information.

TRACKING: 1Z E38 010 06 9193 2545

ID 22960018 Event 1864
Any Business Name

Dear Customer:

UDL is continuing a voluntary Class I nationwide recall of the Actavis Totowa recall of Digitek® (digoxin tablets, USP, all strengths). This product is being recalled due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake.

THIS RECALL IS BEING CONDUCTED TO THE CONSUMER LEVEL.

If you are in possession of any of the recalled lots, quarantine and discontinue distributing, dispensing or taking this product immediately. If you have further distributed this recalled product, please identify your retail-level customers and notify them at once of this recall. Additionally, if the retail-level customers have further distributed the recalled product, please identify the consumer and notify them immediately of this product recall. They should instruct the consumer to contact Stericycle at 1-888-473-8015. Consumers should discuss their treatment options and change in therapy with their physician. Several reports of illnesses and injuries have been received by Actavis.

Please examine your stock, carry out a physical count and record this data on the attached Business Reply Card and Packing Slip. Federal Regulations require a physical count. Federal Regulations also require that you return a completed Business Reply Card even if you do not have the recalled product. Return the Business Reply Card to the address provided. If you have inventory, promptly return the product using the prepaid UPS Return Service shipping labels to:

Stericycle
2670 Executive Drive, Suite A
Indianapolis, IN 46241

ATTN: UDL Digitek® Recall

Credit will be issued for return of recalled product only.

For questions regarding the processing of the Digitek® Tablets (digoxin tablets, USP) recall, please call Stericycle at 1-888-473-8015.

Any adverse reaction experiences with the use of this product, and/or quality problems should also be reported to the FDA MedWatch Program by telephone at 1-800-FDA-1088 or on the MedWatch website at www.fda.gov/medwatch. Also contact Actavis at 1-800-432-8534.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

Sincerely,

Liana M. Radtke

LIANA M. RADTKE
Senior Director Regulatory Affairs/Compliance

1864_0201BD

UDL LABORATORIES, INC.

Urgent: Drug Recall

Digitek® (digoxin tablets, USP)

ALL LOTS WITHIN EXPIRY

Recall initiated by the manufacturer: Actavis Totowa LLC
(formerly known as Amide Pharmaceutical, Inc.)

Product Distributed by: UDL Laboratories, Inc. under a "UDL" Label

April 28, 2008

RE:

Digitek® (Digoxin Tablets, USP) 125 mcg (0.125 mg)
Package Size: UD100 (10 x 10)
NDC 51079-945-20
Lots: 7A666 (Exp. 7/08); 7F048 (Exp. 10/08); 7D352 (Exp. 12/08); 7P862 (Exp. 3/09)
8C515 (Exp. 9/09)

Digitek® (Digoxin Tablets, USP) 125 mcg (0.125 mg)
Package Size: UD300 (10 x 30)
NDC 51079-945-57
Lot: 6S406 (Exp. 5/08)

Digitek® (Digoxin Tablets, USP) 125 mcg (0.125 mg)
Package Size: PC300 (10 x 30)
NDC 51079-945-56
Lot: 7J541 (Exp. 1/09); 7M709 (Exp. 3/09); 7P965 (Exp. 4/09); 8A266 (Exp. 7/09);
8C514 (Exp. 9/09)

Digitek® (Digoxin Tablets, USP) 125 mcg (0.125 mg)
Package Size: CP180 (6 x 30) Compliance Package
NDC 51079-945-66
Lot: 7P964 (Exp. 4/09); 8B371 (Exp. 8/09)

Digitek® (Digoxin Tablets, USP) 250 mcg (0.25 mg)
Package Size: UD100 (10 x 10)
NDC 51079-946-20
Lots: 6S379 (Exp. 5/08); 7C971 (Exp. 9/08); 7J525 (Exp. 1/09); 7V200 (Exp. 6/09)

Digitek® (Digoxin Tablets, USP) 250 mcg (0.25 mg)
Package Size: CP180 (6 x 30) Compliance Package
NDC 51079-946-66
Lot: 7P963 (Exp. 4/09); 8A332 (Exp. 7/09)

1864_0201AD

URGENT: DRUG RECALL

Val Schissel/RCKFRD/MYLAN
05/01/2008 02:52 PM

To "Chris Harvey" <CHarvey@STERICYCLE.com>
cc Sue Powers/RCKFRD/MYLAN@MYLAN, Li Radtke/RCKFRD/MYLAN@MYLAN
bcc
Subject Consumer Kit Approval

The attached has been reviewed and approved.

Valerie Schissel
Regulatory Affairs Labeling Supervisor
UDL Laboratories, Inc.
Val.Schissel@Mylanlabs.com
(815) 654-7260

Consumer Kit Approval 5-1.pdf

EXHIBIT B

1865_CONSUMER

DIGITEK® CONSUMER RETURN KIT

Thank you for your recent inquiry regarding the Digitek® (digoxin tablets, USP) product recall. Stericycle is handling all refund requests associated with the Digitek® product recall. Thus, consumers should not ask their pharmacy for a refund and should follow Stericycle's enclosed instructions to process refund requests. Please read the following information carefully and adhere to the requirements pertaining to your situation.

A. For consumers who are able to return the remaining portion of their Digitek® prescription:

1. Place the unused Digitek®, in its original pharmacy container (if possible), in the enclosed shipping package.
2. Place your valid pharmacy receipt in the enclosed shipping package. A valid pharmacy receipt includes the name, address, and phone number of the dispensing pharmacy, your name, the prescription number, product name, product strength, quantity of product, the date your prescription was filled, and the amount that you paid out-of-pocket for the prescription. Your prescription must have been filled between November 2006 and April 2008 to be eligible for a refund.
3. Complete and sign the *Consumer Authorization Form* at the bottom of this page and include it in the shipping package.
4. Seal the shipping package and affix the prepaid USPS label to the outside and drop in any mailbox.

B. For consumers who destroyed or disposed of the remaining portion of their Digitek® prescription:

NOTE: If you have destroyed or disposed of your Digitek® and cannot return it, you may still be eligible for a refund if you have a valid pharmacy receipt (limited to one receipt) as described in #1 below.

1. Place your valid pharmacy receipt in the enclosed shipping package. A valid pharmacy receipt includes the name, address, and phone number of the dispensing pharmacy, your name, the prescription number, product name, product strength, quantity of product, the date your prescription was filled, and the amount that you paid out-of-pocket for the prescription. Your prescription must have been filled between November 2006 and April 2008 to be eligible for a refund.
2. You must complete and sign the enclosed *Consumer's Certification of Inability to Return Digitek®* and include it in the shipping package.
3. You must also complete and sign the *Consumer Authorization Form* at the bottom of this page and include it in the shipping package.
   Note: Both the *Consumer's Certification of Inability to Return Digitek®* and the *Consumer Authorization Form* must be signed and returned in order to qualify for a refund if you are not returning the Digitek®.
4. Seal the shipping package and affix the prepaid USPS label to the outside and drop in any mailbox.

Eligibility for a refund requires a valid pharmacy receipt (limited to one receipt) as described above indicating that your prescription was dispensed between November 2006 and April 2008. If you are not returning product and you do not have a valid pharmacy receipt, you are not eligible for a refund.

This Consumer Return Kit and required documents must be completed and postmarked no later than **October 31, 2008,** in order to be eligible for a refund. Refund requests may take up to 12 weeks from the time that Stericycle receives the completed Consumer Return Kit.

For shipping assistance and/or questions about the return process, contact Stericycle at **1-888-473-8015.**

CONSUMER AUTHORIZATION FORM: (Signature required)

I understand that the information I have provided in connection with my request for a refund on Digitek® will be used by Stericycle for any purpose related to my request for a refund. As necessary, Stericycle may contact my pharmacy to process my request for a refund and to verify the information I have provided.

By signing below, I authorize Stericycle to use the information I have provided as set forth above. For such purpose, I understand that Stericycle may provide to my pharmacy a copy of this completed Authorization and all other information I have given to Stericycle to process my request for a refund.

Signature: _____ **Print Name:** _____ **Date:** _____

Address: _____ **Telephone:** _____

_____

_____

Stericycle Quality Approval
Initials HH
Date 5-1-08 5-1-08

1865_0101AS

Consumer's Certification of Inability to Return Digitek® (digoxin tablets, USP)
(For consumers who have destroyed or disposed of their Digitek® and cannot return it)

The undersigned certifies as follows:

1. I purchased Digitek® as shown on the valid pharmacy receipt submitted to Stericycle.

2. I still had some unused Digitek® in my possession on April 30, 2008.

3. However, I cannot return my unused Digitek® because I destroyed or disposed of it as described below.

4. I request a refund for this product based on the statements and authorization in this document.

(Please fill in the blanks or check the appropriate boxes below)

Name and address of pharmacy where Digitek® was purchased: _____
_____

Telephone number of pharmacy (if available): ( ) ____ - _____

Amount of Digitek® (number of tablets) I still had in my possession on April 30, 2008:

.25 mg _____ .125 mg _____

I am unable to return this product because:

- ☐ I destroyed or disposed of it
- ☐ I returned it to my physician
- ☐ I returned it to my pharmacy but did not get a refund
- ☐ Other (please explain): _____

I understand that I cannot receive a refund if I keep any portion of unused Digitek® or if I have already received a refund from any other source for this prescription.

Signature: _____ Date: _____

Print name: _____

Address: _____ Telephone: _____

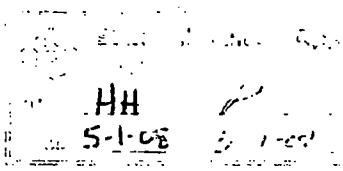
_____

5-1-08 5-1-08

1865_0201AS

6 x 9

Padded Mailer



Insert 3-Side A-Duplex

Urgent: Drug Recall

Digitek® (digoxin tablets, USP)

ALL LOTS WITHIN EXPIRY

Recall initiated by the manufacturer: Actavis Totowa LLC
(formerly known as Amide Pharmaceutical, Inc.)

Product Distributed by: UDL Laboratories, Inc. under a "UDL" Label

Event 1865
ID 22960136
Any Business Name

Below is a listing of affected Digitek® product by NDC number:

NDC	Product Name	Strength	Lot
51079-945-63	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	7P964
51079-945-63	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	8B371
51079-946-63	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	7P963
51079-946-63	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	8A332

If you have affected product or a valid pharmacy receipt please carefully read and follow the instructions on the attached form and place all necessary forms, completed and signed, in the shipping package with your return.

After ensuring all necessary forms are complete and your shipping package is ready to be mailed, remove the prepaid USPS label from the bottom of this page and affix it to the shipping package and drop the in any mailbox.

Please note, if you are not returning product and you do not have a valid pharmacy receipt, you are not eligible for a refund.

Event 1865
ID 22960136
Any Business Name

ID# 22960136 Event 1865
Any Business Name
Any Street
Any City XX 12345

NO POSTAGE NECCESSARY IF MAILED IN THE UNITED STATES

PRIORITY MAIL

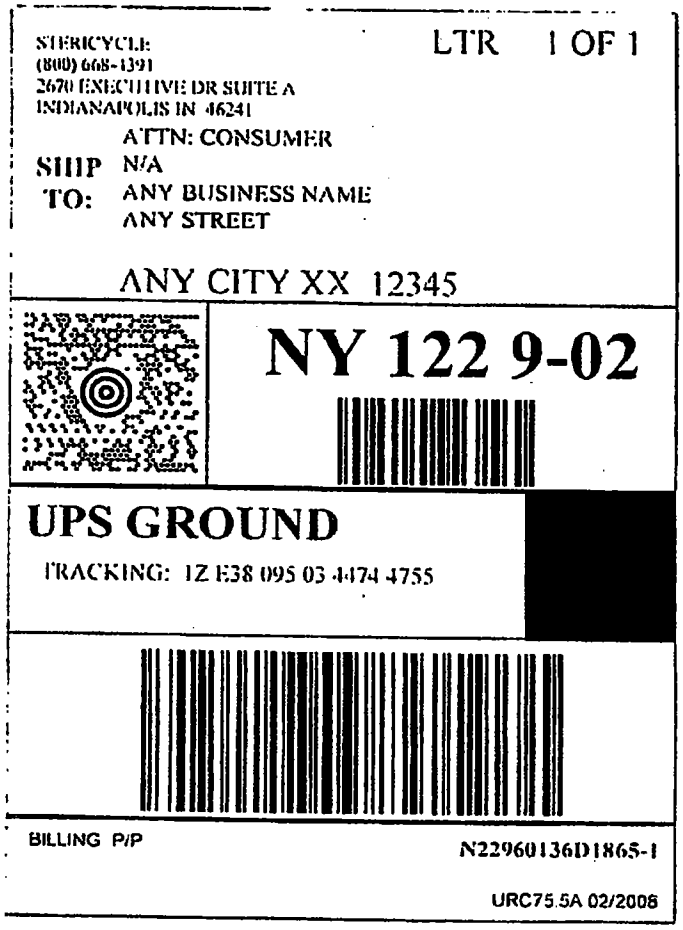
MERCHANDISE RETURN LABEL
PERMIT NO 70005
STERICYCLE
INDIANAPOLIS IN 46241
2670 EXECUTIVE DRIVE

POSTAGE DUE UNIT
US POSTAL SERVICE
PO BOX 9998
INDIANAPOLIS IN 46241-9998

HH
5-1-07

ID 22960136 Event 1865
Any Business Name

Insert 3-Side B-Duplex



STERICYCLE
(800) 668-1391
2670 EXECUTIVE DR SUITE A
INDIANAPOLIS IN 46241
ATTN: CONSUMER

LTR 1 OF 1

SHIP TO: N/A
ANY BUSINESS NAME
ANY STREET

ANY CITY XX 12345

NY 122 9-02

UPS GROUND

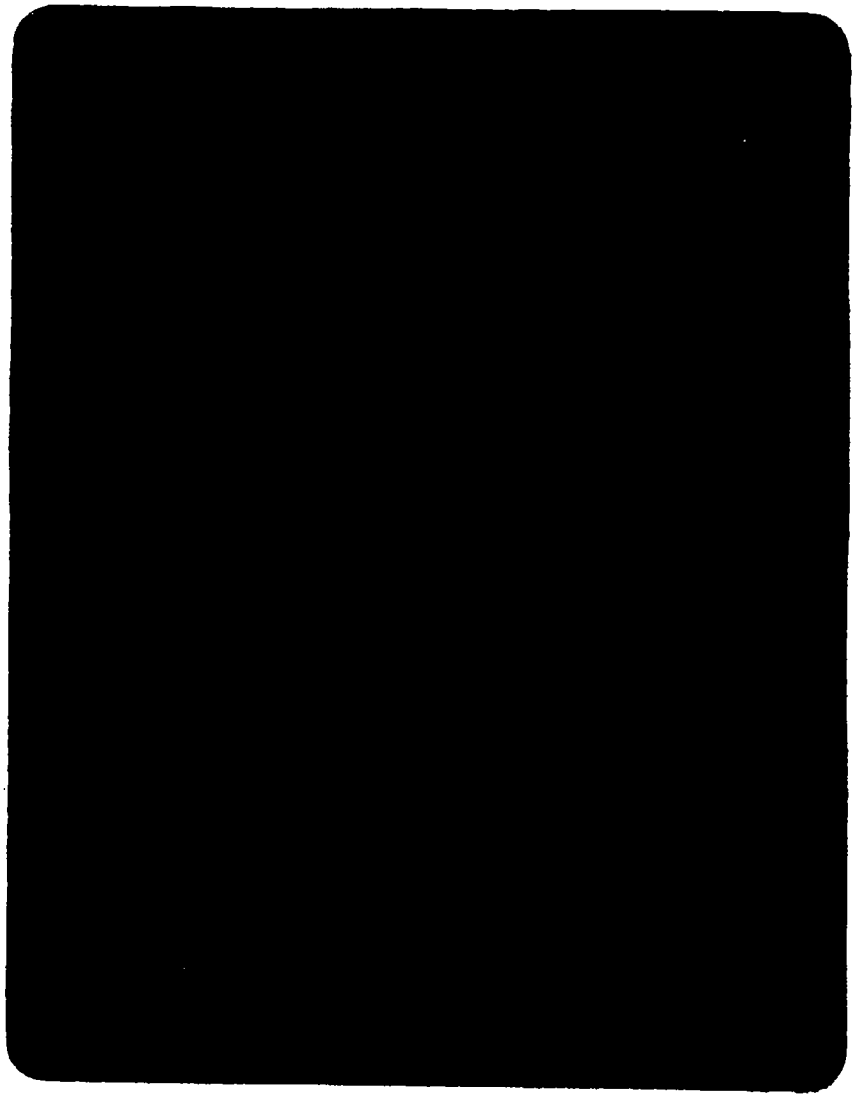
TRACKING: 1Z E38 095 03 4474 4755

BILLING P/P

N22960136D1865-1

URC75.5A 02/2008

HH
5-1-03



URGENT: DRUG RECALL – Red

9 X 12 Window Envelope

HH